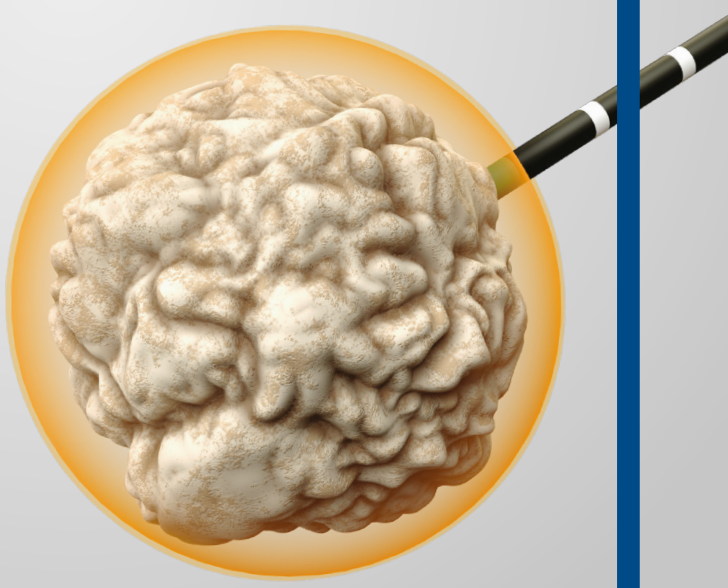
INFORMATION YOU CAN COUNT ON

Manufacturer ablation zone reference values explained



Medtronic
Further, Together

PROVIDING YOU USABLE INFORMATION

We believe sharing clinically relevant ablation information will lead to better care for patients. That's why we strive to provide you with the most clinically relevant ablation zone reference values.

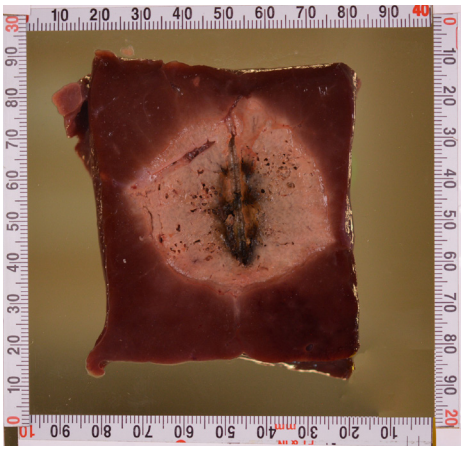
INDUSTRY USES EX VIVO TISSUE MODELS

There is no common standard across manufacturers for tissue model temperatures to produce the ablation zone reference data.

Further, as the tissue model temperature increases, ablation zones get larger.[1]

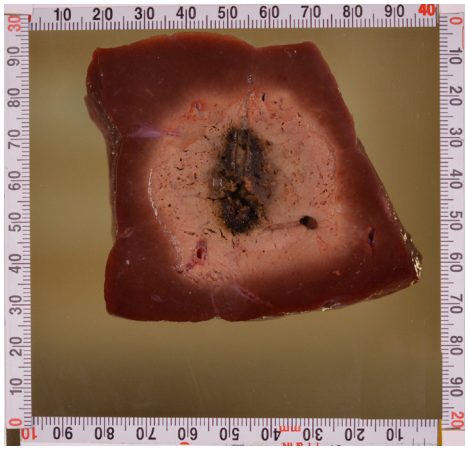
EMPRINT™ ABLATION SYSTEM PERFORMANCE ACROSS VARIED TISSUE MODEL TEMPERATURES (100 W, 10 MIN IN BOVINE LIVER MODEL)[1,2]

17 C
n = 6



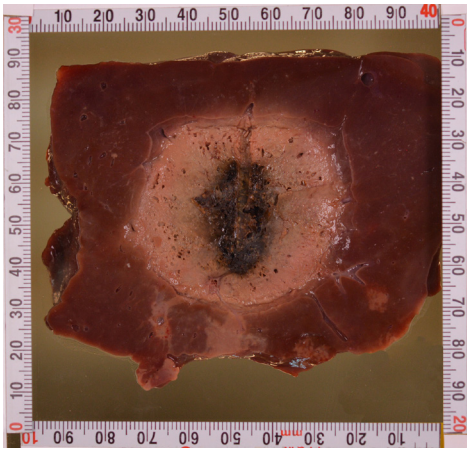
W = 4.2 cm
H = 4.2 cm

25 C
n = 6



W = 4.7 cm
H = 4.5 cm

35 C
n = 6



W = 5.0 cm
H = 4.8 cm

Model temperature has a significant effect on the size of ablation zone created ($P < 0.05$ for all tests[1]).

DISCLAIMER: Animal data is not necessarily indicative of human clinical outcomes.

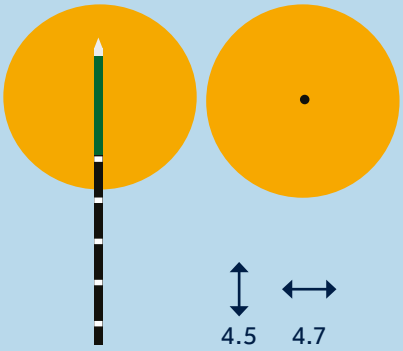
NORMALIZING PERFORMANCE ACROSS SYSTEMS

Since there is no standard model, manufacturers may choose to use any temperature bovine liver model to create ablation zone reference charts. This makes comparing performance across systems difficult. We generated new data to make it clearer.

25 C

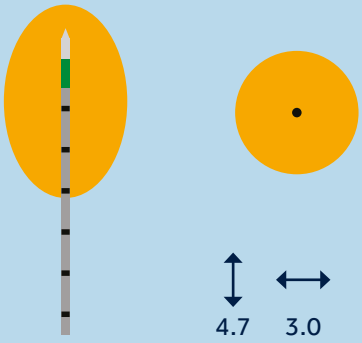
EMPRINT™ ABLATION SYSTEM[1]

Single Probe
100 W, 10 min

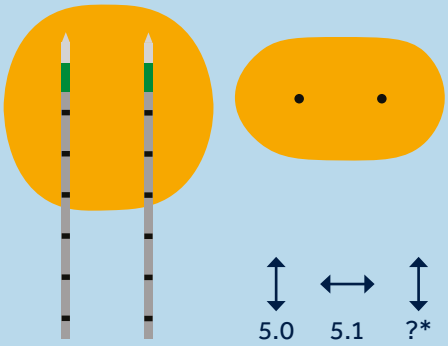


CERTUS 140™ ABLATION PROBES[3,4]

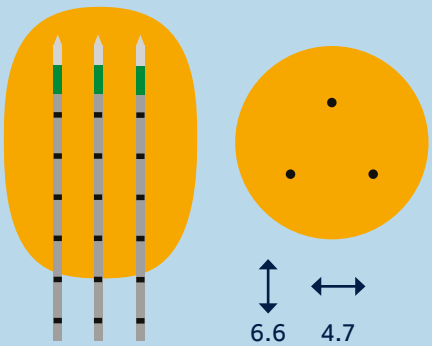
Single Probe
65 W, 10 min



Double Probe
65 W, 10 min



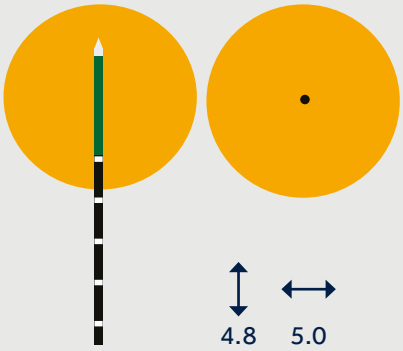
Triple Probe
65 W, 10 min



35 C

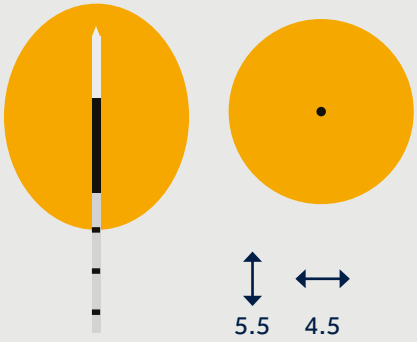
EMPRINT™ ABLATION SYSTEM[1]

Single Probe
100 W, 10 min



ACCU2I PMTA APPLICATORS[5,6]

Single Probe
140 W, 6 min



CURRENT MWA MANUFACTURER MODEL TEMPERATURES

	17 C	25 C	35 C
Medtronic	■		
J&J		■	
Angiodynamics			■
HS Medical[4]		■	

Manufacturer reference values using 25 C liver shows overprediction of ablation zones in comparison to clinical outcomes.[4]

DISCLAIMER: Animal data is not necessarily indicative of human clinical outcomes.

*Dimension not provided by manufacturer

DEFINING CLINICALLY RELEVANT MODELS

We know being predictable matters. That's why we provide ablation reference values from clinically relevant models.

IN VIVO

- Live porcine liver tissue
- Preclinical model simulates in situ organ perfusion

EX VIVO

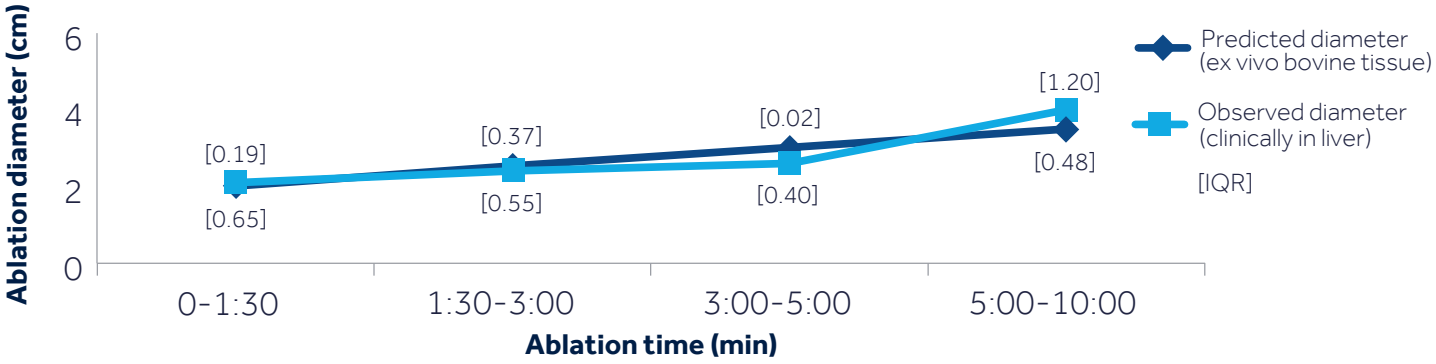
- Bovine tissue, chilled to 17 C
- Chilled tissue calibrates ablation performance to live models[7,8]

EMPRINT™ ABLATION SYSTEM PROUDLY PROVIDES BOTH IN VIVO AND EX VIVO DATA IN OUR INSTRUCTIONS FOR USE.[2,3,5]

THE DIFFERENCE IS PROVEN

Using a clinical relevant model means you see the results you expect.[1]

Comparison of Ablation Zone Diameters: Prediction versus clinical observation at 100 W[9]



References

1. Based on internal test report #RE00100439, Emprint™ variable temperature ex vivo ablation performance evaluation. Statistics for differences in ablation diameter at varying temperatures: 17 C vs. 25 C, P = 0.006; 17 C vs. 35 C, P = 0.001; 25 C vs 35 C, P = 0.03. May 2017.
2. PT00049970 Emprint™ Percutaneous Antenna with Thermosphere™ Technology [instructions for use] Rev 07/2016. Mansfield, MA: Medtronic; 2016.
3. PL-000026 PR Ablation Probes [instructions for use] Rev D 09/2015. NeuWave Medical, Inc; 2015.
4. Winokur RS, Du JY, Pua BB, et al. Characterization of in vivo ablation zones following percutaneous microwave ablation of the liver with two commercially available devices: Are manufacturer published reference values useful? *J Vasc Interv Radiol.* 2014 Dec;25(12):1939-1946.e1.
5. MLC 506 US Rev E. AngioDynamics, Inc.
6. Niemeyer DJ, Simo KA, McMillan MT, et al. Optimal ablation volumes are achieved at submaximal power settings in a 2.45-GHz microwave ablation system. *Surg Innov.* 2015;22(1): 44–45.
7. Based on internal test report #R0043973_B, In vivo performance testing of the Emprint™ MWA system in a porcine model. March 2014.
8. Based on internal test report #R0048333, Emprint™ ablation size test report. Dec. 2013.
9. De Cobelli F, Marra P, Ratti F, et al. Microwave ablation of liver malignancies: comparison of effects and early outcomes of percutaneous and intraoperative approaches with different liver conditions. *Med Oncol.* 2017;34(4):49. Publication compares manufacturer provided ex vivo zone charts generated with bovine tissue to clinical ablation zone performance.

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